## REMARKS

Reconsideration of the application is respectfully requested.

Claims 4, 10-12, 23, and 27-29 have been canceled without prejudice or disclaimer.

Claims 1, 6, 13, 22, and 30 have been amended to clarify the claimed invention and modify claim dependency. Support for the amendments is found throughout the specification (e.g., page 6, lines 11-17 and 30-35), and in canceled claims 10 and 27. No new matter has been added.

Upon entry of this amendment, claims 1-3, 5-9, 13, 22, 24-26, and 30 are pending and under examination.

## Priority

Applicants thank the Examiner for summarizing the priority status of the claims in this application. Applicants note that reference to SEQ ID NO:4 has been removed from the claims currently under examination.

## Claim Objections

Claims 10, 22, and 27 have been objected to because of certain informalities.

Claims 10 and 27 have been canceled thereby rendering the objections moot.

Claim 22 is objected to because, according to the Examiner, the phrase "treatment of overweight" is grammatically incorrect. In response to this objection, claim 22 has been amended to recite a method for inhibiting and/or relieving obesity. Applicants submit that this language clarifies the claim. Therefore, Applicants respectfully request that this objection be withdrawn, accordingly.

**Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 4, 6, 11, 12, 28, and 29 have been rejected as indefinite.

According to the Examiner, claims 4 and 6 are unclear because these claims recite the term "such as..." In response, claim 4 has been canceled thereby rendering this rejection moot. Claim 6 has been amended to delete the term "such as." Therefore, the rejection should be withdrawn as to claim 6.

Claims 11 and 28 have been deemed unclear because they recite the term "similar to," while claims 12 and 29 have been deemed unclear because they recite the phrase "a similarity corresponding to" (*see* Office Action, page 4). According to the Examiner, these terms are unclear because they are not defined by the claims, and the specification does not provide a standard for ascertaining the degree of similarity. *Id.*

Claims 11, 12, 28, and 29 have been canceled, thereby rendering this rejection moot.

**Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 1-13 and 22-30 have been rejected as lacking enablement. According to the Examiner, the specification does not adequately enable the treatment and prophylaxis of the claimed conditions characterized or caused by abnormal loss of cells (*see* Office Action, pages 4-5). The Examiner concludes that the breadth of the claims is greater than what is actually disclosed or enabled in the specification. *Id.*

Claims 4, 10-12, 23, and 27-29 have been canceled without prejudice or disclaimer, thereby rendering this rejection moot as to these claims.

Without conceding the validity of the rejection, claims 1 and 22 have been amended to call for inhibiting and/or relieving obesity or conditions caused or characterized by abnormal loss of cells in the central nervous system by administering a pharmaceutical composition, to

subjects in need thereof, that includes a compound that is at least about 80%, at least about 85%, at least about 90%, at least about 95%, at least about 96%, at least about 97%, at least about 98%, or at least about 99% identical to SEQ ID NO:2.

By way of these amendments, the claims no longer recite "prevention." Instead, the claims call for "inhibiting and/or relieving" conditions that are characterized by an abnormal loss of cells in the central nervous system. The definitions of inhibiting and relieving are explicitly set forth in the specification (*see* specification, page 6, lines 11-17), as well as in the priority document, U.S. Provisional Application No. 60/387,390 (*see* page 17, lines 23-29). Furthermore, the specification discloses that GIP increases proliferation of brain cells (*see, e.g.*, Example 6). This disclosure demonstrates that GIP inhibits and/or relieves conditions causes or characterized by abnormal loss of cells in the CNS. Finally, the claimed structure is now clearly delineated with reference to SEQ ID NO:2.

Accordingly, extensive research would not be required to carry out the claimed method because the compound, the patient population, the condition, and the desired therapeutic effect are each set forth both in the claims and the specification. In any event, a considerable amount of experimentation is permissible if it is merely routine. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). MPEP § 2164.06. Here, the specification provides detailed disclosure to the meaning of "inhibiting" and "relieving," a working example demonstrating the effect of GIP on neural cells, and a specific structure (i.e., sequence listing). These specific parameters provide those skilled in the art with adequate (in fact, detailed) guidance to perform what would merely be routine experimentation, and thereby carry out the claimed method without having to resort to undue experimentation. Therefore, Applicants respectfully request that this rejection be withdrawn.

* * *

Claims 1-13 and 22-30 have been rejected as lacking written description. According to the Examiner, claims 1 and 22 describe screening assays that can identify compounds with

activities similar to SEQ ID NOS: 2 or 4, but lack structurally defined compounds (*see* Office Action, page 10). The Examiner contends that such a screening assay does not support the claimed genus, and that Applicants have not described a reasonable number of members of the genus. The Examiner concludes that the instant claims amount to "reach through" claims (*see* Office Action, page 11).

Claims 4, 10-12, 23, and 27-29 have been canceled without prejudice or disclaimer, thereby rendering this rejection moot as to these claims.

The written description requirement is satisfied when the specification describes "the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." MPEP § 2163(I); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560 (Fed. Cir. 1991). *See University of Rochester v. G. D. Searle & Co., Inc.*, 358 F.3d 916, 921 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002). Furthermore, the written description is adequate if a person of ordinary skill would have understood the inventor to have been in possession of the claimed invention, "even if every nuance of the claims is not explicitly described in the specification." *Vas-Cath, Inc.*, 935 F.2d at 1560. The statute "does not require identical descriptions" in the specification and claims. *Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 208 F.3d 989, 1000 (Fed. Cir. 2000). *See University of Rochester*, 358 F.3d at 922-23 ("claimed subject matter 'need not be described *in haec verba*' in the specification to satisfy the written description requirement"). Thus, we should not "let form triumph over substance" when asking if the claims are reasonably supported by the disclosure. *Union Oil Co. of Calif.*, 208 F.3d at 1001 (*quoting Vas-Cath, Inc.*, 935 F.2d at 1563).

As discussed above, the present claims call for inhibiting and/or relieving obesity or conditions that are characterized by an abnormal loss of cells in the central nervous system by administering compounds with activity of variable identity to SEQ ID NO:2. Inhibiting and relieving are each defined in the specification, as is the claimed amino acid sequence of SEQ ID NO:2. A person of ordinary skill in the art would readily be able to obtain a protein of such a sequence, determine its biological activity, and subsequently determine the activity of variant

proteins that fall within the claimed levels of identity to SEQ ID NO:2. Such related structures could then be used in compounds to inhibit and/or relieve the claimed conditions.

Additionally, Applicants submit that the present claims are not "reach through" claims as asserted by the Examiner. The claims call for methods of inhibiting and/or relieving obesity or conditions characterized by abnormal loss of cells in the central nervous system by administering compounds of variable identity to SEQ ID NO:2. The claimed method does not call for screening of compounds, but rather, the claims specifically call for administering compounds comprising a protein with the amino acid structure of SEQ ID NO:2 or a protein with >80% identity thereof to subjects in need thereof. Therefore, the instantly claimed method is not analogous to the facts in *Rochester* where compounds that inhibit prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2) had to be *identified*. In *Rochester*, compounds that selectively inhibit PGHS-2 activity were *hypothetical*. Here, the compound is the same as, or at least 80% identical to, SEQ ID NO:2. Such a compound, unlike *Rochester*, is not hypothetical or unknown.

Finally, claims 13 and 22 have been amended to remove language encompassing fragments and analogues.

In view of the forgoing, a person of ordinary skill in the art would have recognized that Applicants had possession of the presently claimed invention. Therefore, the written description requirement has been met, and this rejection should be withdrawn.

## Rejections Under 35 U.S.C. § 102

Claims 1-13 and 22-30 have been rejected as anticipated over Bollag (*Molecular and Cellular Endocrinology*, 177:35-41 (2006)). According to the Examiner, claims 1-13 recite prophylaxis and prevention of a disease including administering the disclosed compounds to asymptomatic subjects and therefore anticipates the claimed invention.

Claims 4, 10-12, 23, and 27-29 have been canceled without prejudice or disclaimer, thereby rendering this rejection moot as to these claims.

In order for a reference to anticipate claims under § 102(b), the reference must disclose each and every limitation of the claimed invention, and must be an embodiment of the claimed invention. *Dana Corp. v. Am. Axle & Mfg., Inc.*, 61 USPQ2d 1609 (Fed. Cir. 2002). The teaching must clearly disclose the invention with a certain degree of precision, without the need for picking and choosing components. *Ex parte Westphal*, 223 USPQ 630 (Bd. Pat. App. 1983).

Claims 1 and 22 have been amended to call for "inhibiting and/or relieving" the recited conditions. Additionally, claims 1 and 22 now call for administering the claimed compounds to a subject "in need" of inhibiting or relieving the claimed conditions.

Applicants respectfully submit that Bollag fails to teach each and every limitation of the instant claims because Bollag discloses administering certain compounds to asymptomatic subjects, in contrast to the present claims. Thus, the present invention is not anticipated by the cited reference.

Also, as noted above, the Examiner contends that Bollag teaches that animals that receive the disclosed compound gain weight at the same rate as those animals that do not receive the compound. The Examiner contends that since the animals gained weight no faster than the controls did, the method disclosed by Bollag is reasonable one of preventing obesity and therefore relevant to claims 22-30. However, Bollag discloses that "GIP itself had no effect on weight" (*see* Bollag, page 39, right column, line 15). Therefore, the method disclosed by Bollag in any event does not involve preventing obesity, in contrast to the Examiner's position.

In view of the foregoing, Applicants respectfully request that this rejection be withdrawn.

## CONCLUSION

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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